

Docket No.: 31113/C720  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Gerd Klock et al.

Application No.: 10/582,279

Confirmation No.: 1615

Filed: December 10, 2004

Art Unit: 1633

For: Anti-Apoptotically Active Apatamers

Examiner: S. Long

**RESPONSE PURSUANT TO 37 CFR § 1.143**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This paper is presented pursuant to 37 CFR § 1.143 and in response to the June 21, 2007, non-final official action requiring a nine-way restriction among the pending claims (i.e., claims 1 and 8-16) for examination purposes.

A complete listing of the existing claims is not required (or presented herein) because no changes are being made to the claims, no claims are being canceled, and no claims are being added. *See* 37 CFR § 1.121(c).

**1. The Requirement for Restriction is Traversed****A. The Requirements for Restriction**

This application was filed with ten claims of which claim 1, 9, and 13 are independent. Claim 1 recites “Nucleic acid including a nucleic acid sequence selected from the group consisting of: SEQ ID NOS. 1-9 which is anti-apoptotically active and functional variations of this nucleic acids.” Each of the other dependent claims (i.e., claims 8-12 and 14-16) depends directly from claim 1.

The action requires a nine-way restriction defined by, and alleges that patentably distinct inventions are recited among, the following groups:

Group I, claims 1 and 8-16, drawn to isolated nucleic acids comprising SEQ ID No: 1; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture.

Group II, claims 1 and 8-16, drawn to isolated nucleic acids comprising SEQ ID No: 2; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture.

Group III, claims 1 and 8-16, drawn to isolated nucleic acids comprising SEQ ID No: 3; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture.

Group IV, claims 1 and 8-16, drawn to isolated nucleic acids comprising SEQ ID No: 4; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture.

Group V, claims 1 and 8-16, drawn to isolated nucleic acids comprising SEQ ID No: 5; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture.

Group VI, claims 1 and 8-16, drawn to isolated nucleic acids comprising SEQ ID No: 6; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture.

Group VII, claims 1 and 8-16, drawn to isolated nucleic acids comprising SEQ ID No: 7; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture.

Group VIII, claims 1 and 8-16, drawn to isolated nucleic acids comprising SEQ ID No: 8; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture.

Group IX, claims 1 and 8-16, drawn to isolated nucleic acids comprising SEQ ID No: 9; pharmaceutical preparation thereof; diagnostic kit; and method of manufacture.

As basis for restriction, the action alleges that the inventions listed as Groups I-IX do not relate to a single general inventive under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature since they are allegedly drawn to multiple methods and multiple products.

The requirement is traversed, and reconsideration and withdrawal of the requirements are respectfully requested in view of the following remarks.

**B. The Standard for Requiring Restriction to One of the Nine Groups of Claims Has Not Been Met**

It is respectfully submitted that the action does not provide an adequate basis for the restriction imposed between the claims of the nine groups.

Because this application is the U.S. national phase of an international (PCT) application, unity of invention practice—not restriction practice—is applicable. *See* MPEP § 1893.03(d) (8<sup>th</sup> Ed., Rev. 5, Aug. 2006). Accordingly, the standard for making a lack of unity-of-invention finding requires a showing by the PTO that (a) there are different groups of claims present in one application, and (b) why each of the groups lacks unity relative to each other group, specifically describing the unique special technical feature in each group. *Id.* A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature that defines the contribution, which each claimed invention, when considered as a whole, makes over the prior art. The examiner's attention is directed to the examples in Annex B, Part 2 of the PCT Administrative Instructions as amended July 1, 1992, contained in Appendix AI of the MPEP (8<sup>th</sup> ed., Rev. 2, May 2004).

While the action has set forth nine different groups of claims, it is respectfully submitted that the action provides neither an adequate explanation as to why the claims of each group lack unity relative to the claims of each other group, nor an adequate explanation specifically describing the unique special technical feature in each group. Both explanations are required to support the lack of unity-of-invention rejection. MPEP § 1893.03(d).

### C. PTO's Admissions Concerning the Patentability of the Claims<sup>1</sup>

By imposing restriction among the nine groups of claims, the PTO makes numerous admissions that may compel it to issue numerous patents.

*See, e.g.*, MPEP § 802.01 (8<sup>th</sup> Ed., Rev. 5, Aug. 2006). These admissions are necessary to the PTO's entry of the restriction requirement and may be relied upon by the applicants during examination of this application and future divisional applications, unless the restriction requirement is withdrawn. If the PTO is not making these admissions regarding patentability, then the restrictions should be withdrawn or reexamined under 35 USC § 121 pursuant to the provisions of 35 USC § 372(b)(2).<sup>2</sup>

The restriction requirement also should be withdrawn because the restriction may present potential double patenting. According to the MPEP, the patent statute (e.g., 35 USC § 121):

prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. ... This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a *heavy burden* on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

*See* MPEP § 804.01 (8<sup>th</sup> Ed., Rev. 5, Aug. 2006) (emphasis added). The applicants respectfully request reconsideration and withdrawal of the restriction requirement in view of the foregoing admonitions.

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<sup>1</sup> 35 USC § 372(a) provides that "all questions of substance and, within the scope of the requirements of the treaty and Regulations, procedure in an international application designating the United States shall be determined as in the cases of national applications regularly filed in the Patent and Trademark Office." Accordingly, the effects of restricting claims in the PTO are the *same* whether the unity of invention standard of PCT Rule 13 or the independent and distinct inventions standard of 35 USC § 121 is applied as the basis for restriction.

<sup>2</sup> 35 USC § 372(b)(2) states that "the Director may cause the question of unity of invention to be reexamined under section 121 of this title, within the scope of the requirements of this treaty and the Regulations."

**D. Search and Examination of the Claims in the Various Groups Can Be Made Without Serious Burden on the PTO**

According to the MPEP, a requirement for restriction between multiple inventions is proper only when the PTO establishes (1) that the claimed inventions are independent or distinct, *and* (2) there would be a serious burden on the examiner if restriction were not required:

If the search and examination of all the claims in an application can be made without serious burden, *the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.*

MPEP § 803 (8<sup>th</sup> Ed., Rev. 5, Aug. 2006) (emphasis added).

The applicants acknowledge that “a serious burden on the examiner *may* be prima facie shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02 [(8<sup>th</sup> Ed., Rev. 5, Aug. 2006)].” MPEP § 803(II). The PTO’s action, however, alleges no such burden.

The claims of the various Groups I through IX are concerned with and recite similar subject matter. Specifically, this application was filed with 10 claims of which only claim 1 (Group I) is independent. Claim 1 recites Nucleic acid including a nucleic acid sequence selected from the group consisting of: SEQ ID NOS. 1-9 which is anti-apoptotically active and functional variations of this nucleic acids. Each of the other pending claims (i.e., claims 8-16) depends either directly or indirectly from claim 1. Thus, the various groups are all related to Group I.

Accordingly, separate searches (even though not alleged by the action to be necessary) would *not* constitute a serious burden. Indeed, the PTO has not even alleged that there would be a serious burden (in contravention of the examination procedure set forth at MPEP § 803). Because search and examination of the subject matter recited in the various Groups can be performed without serious burden on the PTO, requiring the applicants to prosecute those claims in separate patent applications would waste the time, effort, and resources of both the applicants and the PTO. Furthermore, the applicants will likely incur additional prosecution costs associated with filing multiple divisional applications and the PTO will be required to perform duplicative searches if the restriction requirement is

maintained. Thus, withdrawal of the restriction requirement will actually *reduce* the burden on the PTO and on the applicants.

In view of the foregoing, the applicants respectfully request reconsideration and withdrawal of the restriction requirement.

## **II. Provisional Election**

Pursuant to the requirements of 37 CFR § 1.143, the applicants hereby elect the subject matter recited in Group I (claims 1 and 8-16, SEQ ID NO:1) for further prosecution.

Should the subject matter recited in the Group I claim be found allowable, the applicants respectfully request that the PTO reconsider the restriction requirement and requests rejoinder of the subject matter recited in the non-elected claims. *See* MPEP § 821.04(a) (8<sup>th</sup> ed., Rev. 5, Aug. 2006).

**CONCLUSION**

Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, the examiner is urged to contact the undersigned attorney.

July 23, 2007

Respectfully submitted,

By \_\_\_\_\_  
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